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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/594,188 | 06/21/2007 | Eugen Kolossov | 2590.0040002/EJH/UWJ | 7273 |

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| EXAMINER | |
|---|---|
| CHEN, SHIN LIN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1632 | |
| **MAIL DATE** | **DELIVERY MODE** |
| 10/16/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/594,188 | KOLOSSOV ET AL. | |
| | Examiner | Art Unit | |
| | Shin-Lin Chen | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-19 and 31-33, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are cardiomyocytes.

Group II, claim(s) 1-19, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are neurons.

Group III, claim(s) 1-19, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are endothelial cells.

Group IV, claim(s) 1-19, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are epithelial cells.

Group V, claim(s) 1-19, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are hepatocytes.

Group VI, claim(s) 1-19, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are fibroblasts.

Group VII, claim(s) 1-19, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are skeletal muscle cells.

Group VIII, claim(s) 1-19, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are smooth muscle cells.

Group IX, claim(s) 1-19, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are chondrocytes.

Group X, claim(s) 1-33, drawn to a method for producing embryoid bodies (EBs) from multi- or pluripotent cells with or without mouse fibroblast feeder cells, an embryoid body obtained by said method, and a differentiated cell or tissue derived from the EB, wherein the cells are cardiomyocytes and are genetically engineered.

Group XI, claim(s) 34-40, drawn to a method for identifying and/or obtaining a drug or for determining the toxicity of a compound by using the embryoid body of claim 31.

Group XII, claim(s) 41 and 42, drawn to a pharmaceutical composition comprising the embryoid body of claim 31 or the cell or tissue of claim 32 or 33, and the use of the embryoid body or the cell or tissue for loss of function assays of specific genes.

Group XIII, claim(s) 41 and 42, drawn to a pharmaceutical composition comprising the embryoid body of claim 31 or the cell or tissue of claim 32 or 33, and the use of the embryoid body or the cell or tissue for gain of function assays of exogenous genes.

Group XIV, claim(s) 41 and 42, drawn to a pharmaceutical composition comprising the embryoid body of claim 31 or the cell or tissue of claim 32 or 33, and the use of the embryoid body or the cell or tissue for developmental analysis of teratogenic/embryotoxic compounds.

Group XV, claim(s) 41 and 42, drawn to a pharmaceutical composition comprising the embryoid body of claim 31 or the cell or tissue of claim 32 or 33, and the use of the embryoid body or the cell or tissue for pharmacological assays.

Group XVI, claim(s) 41 and 42, drawn to a pharmaceutical composition comprising the embryoid body of claim 31 or the cell or tissue of claim 32 or 33, and the use of the embryoid body or the cell or tissue for microarray systems.

Group XVII, claim(s) 41 and 42, drawn to a pharmaceutical composition comprising the embryoid body of claim 31 or the cell or tissue of claim 32 or 33, and the use of the embryoid body or the cell or tissue for establishment of model systems for pathological cell functions.

Group XVIII, claim(s) 41 and 42, drawn to a pharmaceutical composition comprising the embryoid body of claim 31 or the cell or tissue of claim 32 or 33, and the use of the embryoid body or the cell or tissue for application of differentiation and growth factors for induction of selectively differentiated cells.

Group XIX, claim(s) 41 and 42, drawn to a pharmaceutical composition comprising the embryoid body of claim 31 or the cell or tissue of claim 32 or 33, and the use of the embryoid body or the cell or tissue for a source for tissue graft.

Group XX, claim(s) 43, drawn to kit comprising culture media components, selectable markers, reference sample, microarrays, vectors, probes, containers or multi- or pluripotent cells.

Group XXI, claim(s) 44, drawn to use of a cell container, devices, culture media and component thereof, or multi- or pluripotent cells, vectors, fluorescence reader or microscope, or a microarray for a method of any of claims 1-30 or 34-40.

2. The inventions listed as Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The putative special technical feature shared by groups I-XXI is a method for producing embryoid body (EB) from multi- or pluripotent cells, or the embryoid body, or cells or tissue produced from said embryoid body. Thomson et al., 2003 (US Patent No. 6,602,711) teaches a method for producing primate embryoid bodies from colonies of primate embryonic stem cells by removing the adhering colonies of the embryonic stem cells from the subtrate in clumps and then incubating the clumps in a container under conditions that essentially inhibit the clumps from attaching to the container (e.g. claim 1). Further, Benbenisty, Nissim, 2002 (US 20020146678 A1) teaches a method for directing differentiation of human embryonic stem cells to a specific cell type by forming embryoid bodies from human embryonic stem cells, dissociating the embryoid bodies to provide embryonic cells for differentiating in the presence of at least one exogenous factor for an effective period of time, and causing directed differentiation of human embryonic stem cells to form the specific cell type (e.g. [0011]). The human embryonic stem cells were grown on a feeder layer of mouse embryonic fibroblasts (e.g. [0059]). Therefore, there is no special technical feature that is contributed by the instant invention over the prior art. Thus, Groups I-XXI do not relate to a single general inventive concept under PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.
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Primary Examiner
Art Unit 1632